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WASHINGTON, D.C. 20231
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JUN 21 2001

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#10

In re Application of :
Alan G. Baxter :
Serial No.: 09/308,192 : PETITION DECISION
Filed: July 14, 1999 :
Attorney Docket No.: 22975200600 :

This is in response to applicants' petition under 37 CFR 1.144, filed February 20, 2001, requesting withdrawal of an improper lack of unity requirement.

A review of the file history shows that this application was filed under 35 U.S.C. 371 as the National Phase of PCT/AU97/00770. The application, as filed, contains claims 1-22. In a first Office action mailed July 25, 2000, the examiner set forth a restriction/lack of unity requirement under 35 U.S.C. 121 dividing the claims into six groups, as follows:

- Group I, claims 1-4, 7-10 and 20-21, drawn to a treatment method for autoimmune diabetes;
- Group II, claims 1, 5-10, 20 and 22, drawn to a treatment method for anti-tumor response carcinoma;
- Group III, claims 11-14, drawn to a method of treatment in pancreas transplant replacement;
- Group IV, claims 11-14, drawn to a treatment method for IDDM;
- Group V, claims 15-16, drawn to a composition of MAPG;
- Group VI, claims 17-19, drawn to a method of isolating components of MAPG.

Applicants elected Group I, with traverse as to Group II, in reply to the Office action. Applicants argued that the restriction was improper according to PCT guidelines and that the claims of Groups I and II should be examined together based on use of the same components - cell wall components of *Mycobacterium*, in the treatment methods. No traverse of Groups III-VI was made. The examiner considered the traversal, but maintained the lack of unity requirement based on the treatment methods involving different objectives, method steps and final outcomes and made the requirement Final in the Office action mailed December 14, 2000. This petition followed. Petitioner argues that the examiner held that the claims lack unity based on the use of the *mycobacterium* cell wall components in immunomodulatory therapy as exemplified by Adams et al (cited in the International Search Report). However applicant argues that the examiner failed to cite Adams et al in the Office action relying on other references to reject the elected invention

over prior art. Applicant argues that this is tacit support that Adams et al fails to support the examiner's conclusions for maintaining the lack of unity requirement. Applicant further argues that several claims are common to both Groups I and II and there is no evidence to support a holding of multiple inventions in these claims.

DISCUSSION

The applicable guidance for making lack of unity/restriction requirements is set forth below:

Annex B of the PCT Administrative Instructions gives guidance on Unity of Invention as follows:

(a) Unity of Invention. Rule 13.1 deals with the requirement of unity of invention and states the principle that an international application should relate to only one invention or, if there is more than one invention, that the inclusion of those inventions in one international application is only permitted if all inventions are so linked as to form a single general inventive concept.

(b) Technical Relationship. Rule 13.2 defines the method for determining whether the requirement of unity of invention is satisfied in respect of a group of inventions claimed in an international application. Unity of invention exists only when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding special technical features. The expression special technical features is defined in Rule 13.2 as meaning those technical features that define a contribution which each of the inventions, considered as a whole, makes over the prior art. The determination is made on the contents of the claims as interpreted in light of the description and drawings (if any).

(c) Independent and Dependent Claims. Unity of invention has to be considered in the first place only in relation to the independent claims in an international application and not the dependent claims. By dependent claim is meant a claim which contains all the features of another claim and is in the same category of claim as that other claim (the expression category of claim referring to the classification of claims according to the subject matter of the invention claimed for example, product, process, use or apparatus or means, etc.).

(i) If the independent claims avoid the prior art and satisfy the requirement of unity of invention, no problem of lack of unity arises in respect of any claims that depend on the independent claims. In particular, it does not matter if a dependent claim itself contains a further invention. Equally, no problem arises in the case of a genus species situation where the genus claim avoids the prior art. Moreover, no problem arises in the case of a combination subcombination situation where the subcombination claim avoids the prior art and the combination claim includes all the features of the subcombination.

(ii) If, however, an independent claim does not avoid the prior art, then the question whether there is still an inventive link between all the claims dependent on that claim needs to be carefully considered. If there is no link remaining, an objection of lack of unity a posteriori (that is, arising only after assessment of the prior art) may be raised. Similar considerations apply in the case of a genus species or combination subcombination situation.

As explained above, the examiner must first look to the independent claims to determine whether unity of invention exists. This the examiner has done according to part (c) above with respect to independent claims 1, 11, 15 and 17, placing them in different groups as lacking unity because there is no special technical feature relating them to each other. Further consideration was then given to each independent claim to determine whether they encompassed more than one independent and distinct invention. Claims 1 and 11 were found to meet this criteria. With respect to claim 1, it was determined that it encompassed within the claims dependent on it two independent inventions. (See 37 CFR 1.475(e).) Claim 1, per se, relates only to methods of treatment by administering *mycobacterium* cell wall components and analogs or equivalents. As evidenced by Adams et al (and 17 other references cited on the International Search Report and applied in the International Examination Report) these components are known in the prior art and cannot be relied on as the special technical feature to support unity of invention. A review of the dependent claims shows that they relate to two separate and distinct methods of treatment for two distinctly different conditions, specifically an autoimmune disease identified as diabetes and an anti-tumor immune response identified as cancer. Thus the special technical feature on which lack

of unity is based is the combination of the disease or condition being treated and the treatment agent (the *mycobacterium* components). Because the diseases are unrelated to each other as well as their cause and their treatment, lack of unity exists. Petitioner's argument that the examiner failed to use Adams et al in rejecting the claims at issue is irrelevant. The examiner is presumed to have used the best prior art to reject the examined claims. Adams et al (as well as many other references) is sufficient to show that the *mycobacterium* cell components are well known in the art and cannot be used to establish unity of invention as could any of the other references actually used in the prior art rejection.

DECISION

Applicants' petition is **DENIED** with respect to any error in finding lack of unity between Groups I and II. No traversal of the requirement between Groups III-VI has been requested or considered.

The application will be forwarded to the examiner for further consideration no inconsistent with this decision..

Should there be any questions with respect to this decision, please contact William R. Dixon, Jr., by mail addressed to: Director, Technology Center 1600, Washington, D.C. 20231, or by telephone at (703)308-3824 or by facsimile transmission at (703) 305-7230..

Any request for reconsideration of this decision must be made within TWO MONTHS of the mailing date of this decision and should be addressed to the Office of Petitions.



Jasmine Chambers
Director, Technology Center 1600